UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

KEITH EDWARDS,

Plaintiff,

v.

Case No.: 2:05-cv-657
JUDGE SMITH
Magistrate Judge Abel

WARNER-LAMBERT, *et al.*,

Defendants.

OPINION AND ORDER

Plaintiff Keith Edwards, acting *pro se*, initiated this action in 2004 in the Franklin County Court of Common Pleas. In his Complaint, Plaintiff alleged fraud and civil conspiracy claims against Defendants Warner-Lambert LLC, Parke-Davis Co., and Pfizer, Inc. ("Defendants")[1]. The case was removed to this Court in 2005. The case was then transferred to the United States District Court for the District of Massachusetts on August 15, 2005. The case was then officially remanded back to this Court on May 24, 2011, based on a finding by the Court in the District of Massachusetts that all remaining issues are case-specific. (*See* Docs. 10 and 15).

The Defendants previously moved for judgment on the pleadings. (Doc. 24). The court withheld ruling on the initial motion for judgment on the pleadings in order to provide the Plaintiff with an opportunity to amend his complaint to substantiate his fraud claim. Plaintiff filed his Amended Complaint (doc. 30) on January 19, 2012. Defendants have now filed a second Motion

[1]Defendant Parke-Davis is a division of Warner-Lambert which is now owed by Pfizer, Inc.

for Judgment on the Pleadings in response to the Amended Complaint (Doc. 31). Plaintiff has responded and this matter is now ripe for review. For the reasons that follow, Defendants' Motion is **GRANTED**.

I. BACKGROUND

On or about April 12, 2002, through April 15, 2002, Plaintiff Keith Edwards was an inmate under the custody, care and control of the Ohio Department of Rehabilitation and Correction. Plaintiff Edwards was transferred from the Richland Correctional Institution to the Corrections Medical Center for an unrelated medical problem. While at the medical facility, Plaintiff was overdosed 9,000 mg of Crizivan over a seventy-two hour period. As a result of this alleged overdose, Plaintiff suffered elevated blood pressure, elevated liver ALT levels, exacerbation of pain and numbness to his lower legs and feet, increased levels of HIV viral loan and/or complications, placing Plaintiff in jeopardy that his immune system might fail. Plaintiff asserts that as a result of the prior medication error, he was prescribed Neurontin to treat the nerve pain and numbness that he was experiencing in his lower legs and feet. Plaintiff was administered the drug Neurontin for over one and a half years. (Pl.'s Amended Compl. ¶1). Plaintiff claims that as a result of taking Neurontin, he suffered from fatty tumors, stomach problems (convulsions), sleep disorder, nervousness and severe depression, and thoughts of suicide.

Plaintiff alleges that Defendant Warner-Lambert marketed Neurontin to treat a wide array of ailments for which the drug was not approved, such as bipolar mental disorder, various pain disorders, Amyotrophic Lateral Sclerosis ("ALS"), attention deficit disorder, migraine headaches, drug and alcohol withdrawal seizures, restless leg syndrome, and epilepsy. On January 15, 1992,

Parke-Davis (a division of Warner-Lambert) submitted a New Drug Application ("NDA") to the FDA seeking approval for Neurontin as an adjunctive therapy for epilepsy. As part of its submission, Parke-Davis submitted data documenting adverse events reported in its clinical trials. For example, seventy-eight individuals, or 5.3 percent of the total exposed patient population of the NDA, reported depression as an adverse event. Seven instances of depression were categorized as "serious" events, and nine patients withdrew from studies because of depression. There were also numerous mood and behavioral disturbances, or "psychobiologic" adverse events, reported in the studies. The FDA concluded its review of Neurontin's NDA by stating that Neurontin was "approvable with appropriate and prominent labeling for use in a specific population."

On or about December 15, 1992, the Peripheral and Central Nervous System Drugs Advisory Committee to the Department of Health and Human Services voted to recommend Neurontin for a very specific use in a limited population, the adjunctive treatment for refractory epilepsy. Approximately one year later, on December 30, 1993, the company received FDA approval to market Neurontin for the adjunctive treatment of epilepsy in adults. The FDA stated that the drug is only effective at 900 to 1800 milligrams per day. Later, in 2002, the FDA approved Neurontin for the management of post-herpetic neuralgia (pain resulting from nerve damages caused by shingles or herpes zoster) in adults.

Beginning in 1995, Defendants engaged in a multi-faceted marketing campaign designed to increase off-label sales of Neurontin. Defendants began to illegally market and promote the sale of Neurontin for "off-label uses" which were not approved by the FDA, such as the treatment of pain, bipolar disorder and anxiety. Sales representatives made presentations to doctors' offices

promoting Neurontin for pain and for reflex sympathetic dystrophy, a nerve damage syndrome. Defendants trained their sales representatives to promote off-label uses and motivated sales representatives to encourage prescription amounts for dosages higher than approved by the FDA. Additional off-label usages of Neurontin that were promoted by Defendant were for a variety of conditions including migraines, post-herpetic neuralgia, restless leg syndrome, bipolar disorder, and "ALS". Medical liaisons also falsely informed doctors that early results from clinical trials evaluating Neurontin for the treatment of bipolar disorder, peripheral and diabetic neuropathy, and other pain syndromes, indicated 90% response rates.

Clinical evidence emerged from the FDA trials that did not support Pfizer's promotion of Neurontin as safe and effective for off-label uses. Defendants and their representatives nonetheless promoted off-label uses even where there was contradictory clinical evidence. For example, Defendants sponsored a study conducted at the Harvard Bipolar Research Program in 1998, which concluded that patients receiving Neurontin did worse than those patients on placebo sugar pills. Although Defendants were aware of the results of this study, they did not publish the study's results until 2000, after a significant number of physicians were induced to prescribe Neurontin.

Defendant Warner-Lambert Company LLC was charged in the United States District Court for the District of Massachusetts with improper off-label marketing in violation of 21 U.S.C. §§ 331(a), 331(d), 333(a)(2), 352(f)(1) and 355(a), and pled guilty to the charges on June 7, 2004.

In his Amended Complaint, the Plaintiff alleges that Defendants violated his rights under the Eighth and Fourteenth Amendments to the United States Constitution by committing

violations of the Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §301, *et seq*. Specifically, Plaintiff alleges that Defendants violated sections 331(a), 331(d), 333(a)(2), 353(f)(1) and 355(a) of the FDCA.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(c) provides that "[a]fter the pleadings are closed-but early enough not to delay trial-a party may move for judgment on the pleadings." It is well-settled that the standard of review for a motion for judgment on the pleadings under Rule 12(c) is the same as that used to address a motion to dismiss under Rule 12(b)(6). *See, e.g.*, *Lindsay v. Yates*, 498 F.3d 434, 438 (6th Cir. 2007); *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 11 (6th Cir. 1987) (noting that where a Rule 12(b)(6) defense of failure to state a claim upon which relief may be granted is raised by a Rule 12(c) motion for judgment on the pleadings, the Court must apply the standard for a Rule 12(b)(6) motion).

Rule 12(b)(6) permits dismissal of a lawsuit for "failure to state a claim upon which relief can be granted." A Rule 12(b)(6) motion to dismiss is directed solely to the complaint and any exhibits attached to it. *Roth Steel Prods. v. Sharon Steel Corp.*, 705 F.2d 134, 155 (6th Cir. 1983). The merits of the claims set forth in the complaint are not at issue on a motion to dismiss for failure to state a claim. Consequently, a complaint will be dismissed pursuant to Rule 12(b)(6) only if there is no law to support the claims made, or if the facts alleged are insufficient to state a claim, or if on the face of the complaint there is an insurmountable bar to relief. *See Rauch v. Day & Night Mfg. Corp.*, 576 F.2d 697, 702 (6th Cir. 1978). Rule 12(b)(6) must be read in conjunction with Rule 8(a) of the Federal Rules of Civil Procedure, which requires the complaint

to contain a "short and plain statement of the claim showing that the pleader is entitled to relief[.]"

A court, in considering a 12(b)(6) motion to dismiss, must "construe the complaint in the light most favorable to the plaintiff," accepting as true all the plaintiff's factual allegations. *Gunasekera v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009). Although in this context all of the factual allegations in the complaint are taken as true, a court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Consequently, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009).

Furthermore, to survive dismissal pursuant to Rule 12(b)(6), a claim must contain sufficient factual matter to "state a claim to relief that is plausible on its face." *Twombly*, at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, at 1950. While a complaint need not contain "detailed factual allegations," its "factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true." *Twombly*, at 555. "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.' " *Iqbal*, at 1950 (quoting Fed. Rule Civ. Proc. 8(a)(2)). In the final analysis, the task of determining plausibility is "context-specific [and] requires the reviewing court to draw on its judicial experience and common sense." *Id.*

Accordingly, the Court will grant a motion for judgment on the pleadings if there is an absence of law to support a claim of the type made, or of facts sufficient to make a valid claim, or if on the face of the complaint there is an insurmountable bar to relief indicating that the plaintiff does not have a claim. *Little v. UNUM Provident Corp.*, 196 F. Supp.2d 659, 662 (S.D. Ohio 2002) (Graham, J.) (citing *Rauch*). Stated differently, "[f]or purposes of a motion for judgment on the pleadings, all well-pleaded material allegations of the pleadings of the opposing party must be taken as true, and the motion may be granted only if the moving party is nevertheless clearly entitled to judgment." *JPMorgan Chase Bank, N.A. v. Winget*, 510 F.3d 577, 581 (6th Cir. 2007) (internal citations and quotation marks omitted).

III. DISCUSSION

Defendants Warner-Lambert LLC, Parke-Davis Co., and Pfizer Inc. move for judgment on Plaintiff's Amended Complaint. Defendants argue that the plaintiff has amended his complaint so as to no longer allege a fraud or civil conspiracy claim, but rather to assert only a claim for violation of the FDCA. Defendants argue that because there is no private right of action under the FDCA, the Amended Complaint should be dismissed. Defendants also argue that the plaintiff's reference to the Ohio Product Liability Act ("OPLA"), Ohio Revised Code § 2317.71 *et seq.* in his Memorandum in Opposition is insufficient to state a claim for violation of the OPLA. Plaintiff's response appears to be that he has retained his fraud claim and is using the Defendant's violations of the FCDA as the requisite proof required to succeed on the fraud claim. In his response, the plaintiff also alleges violation of the OPLA. Both the Amended Complaint and plaintiff's response fail to re-raise his civil conspiracy claim.

A. Food, Drug and Cosmetic Act (FDCA)

The FDCA is a "public protection statute, one designed, among other things, to keep misbranded and/or adulterated articles from entering interstate commerce." *Griffin v. O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717, 718 (S. D. Ohio 1985) (citing *United States v. Walsh*, 331 U.S. 432, 434 (1947)). It is well-settled that there is no private right of action under the FDCA. *See Buckrnan Co v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (there is "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance" with the FDCA); *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA"); *Griffin v. O'Neal, Jones & Feldman, Inc.*, 604 F. Supp. 717, 718 (S.D. Ohio 1985) ("It is clear from the face of the statute that no civil private right of action exists"). Accordingly, Plaintiff may not maintain a cause of action against the Defendants for violations of the FCDA and this claim is dismissed.

B. Fraud Claim

The Amended Complaint seeks relief for Defendants' violations of the FDCA. There is no prayer for relief on the grounds that Defendants committed a fraud. Even if the court were to construe the complaint liberally so as to include a claim for fraud, the Plaintiff's claim for fraud would necessarily fail for two reasons.

First, any purported claim for fraud which could arguably be ascertained from the Amended Complaint would rely on the admitted violations of the FDCA as proof of the alleged fraud. However, "the absence of a private right of action to enforce the FDCA means that not only is a private party precluded from bringing suit to enforce the provisions of the FDCA, they

also 'may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA.'" *Loreto v. P&G*, 737 F. Supp. 2d 909, 919 (S.D. Ohio 2010) (citing *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp.2d 1282, 1290-1291 (C.D. Cal. 2008)). Accordingly, a "purported state-law claim does not exist where the 'claim is in substance (even if not in form) a claim for violating the FDCA - that is, when the state claim would not exist if the FDCA did not exist.'" *Id.* (citing *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). Thus, even if Plaintiff is alleging fraud, the factual basis for that claim is entirely reliant on the FDA's case against Defendants for violation of the FDCA. (*See* Amended Complaint and Dept. Of Justice News Release at Doc. 25–1(Ex. A)). The Plaintiff relies solely on the fact that defendants engaged in off-label marketing to induce physicians to use Neurontin as proof of Defendants' fraud. Accordingly, because Plaintiff is suing for conduct that violates the FDCA, he cannot maintain a fraud claim on these grounds.

Second, even if the Plaintiff's claim for fraud was arguably based on conduct outside the FDCA, it fails because it does not comply with the requirements of Federal Rules of Civil Procedure 9(b). Rule 9(b) provides that: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." In order to meet the requirement that fraud be pled with particularity, the complaint must, at a minimum, allege the "time, place and content of the alleged misrepresentation on which [the deceived party] relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 518 (6th Cir. 2009) (internal citations omitted). Plaintiff fails to allege any facts specifically related to his receipt of Neurontin that meet

the particularity requirements of Rule 9(b). There are no allegations as to the "time, place or content" of any representation made either to plaintiff or to his particular prison physicians. As there is no allegation that misrepresentations were made by defendants specifically to plaintiff or his physicians, there can be further no allegation that plaintiff or his physicians relied on any mispresentation. Accordingly, plaintiff's Amended Complaint fails to set forth a claim for fraud and any such purported claim is dismissed.

C. OPLA

In his response in opposition to the Motion for Judgment on the Pleadings (but not in the Amended Complaint), plaintiff purports to assert a product liability claim under the OPLA. "It is axiomatic that a plaintiff cannot add new claims to [his] complaint in an opposition to a motion to dismiss." *Ault v. Medina Med. Investors, LLC*, No. 1:06cv1113, 2007 U.S. Dist. LEXIS 1407 (N.D. Ohio Jan. 8, 2007). Accordingly, any purported claim for liability under the OPLA can be dismissed on this ground alone *Id.*

Moreover, even if the court were to consider the OPLA claim as properly raised, Defendants would still be entitled to judgment on this claim. The Plaintiff's response merely recites the definition of a product liability claim as it is defined in the OPLA. *See* Ohio Rev. Code §2307.71(A)(13). There are no factual allegations anywhere within the Amended Complaint to support a claim under the OPLA. Accordingly, plaintiff cannot maintain a claim against defendants under the OPLA.

IV. DISPOSITION

For the foregoing reasons, the Court **GRANTS** Defendant's Motion for Judgment on the Pleadings (doc. 31). If the Defendants intend to pursue the Court's earlier award of attorney's

fees (Docs 32, 39), then the Defendants shall submit an affidavit and supporting evidence relating to the amount of fees sought pursuant to the Court's earlier Order. Such affidavit and evidence shall be filed within fourteen (14) days of the date of this Order. Upon receipt of the Defendant's request for fees, the Court will consider the Plaintiff's outstanding Motion to Defer Attorney's Fees (Doc 40).

IT IS SO ORDERED.

s/ George C. Smith
GEORGE C. SMITH, JUDGE
UNITED STATES DISTRICT COURT